



**THIS LETTER CONTAINS ~~PROPRIETARY AND EXPORT CONTROLLED INFORMATION~~
IN ACCORDANCE WITH 10 CFR 2.390**

June 17, 2020

2020-SMT-0053
10 CFR 50.30

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

50-608

- References:
- (1) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
 - (2) NRC letter to SHINE Medical Technologies, LLC, "Issuance of Request for Additional Information Related to the SHINE Medical Technologies, LLC Operating License Application (EPID No. L-2019-NEW-0004)," dated May 26, 2020 (ML20148M278)

SHINE Medical Technologies, LLC Operating License Application
Response to Request for Additional Information

Pursuant to 10 CFR Part 50.30, SHINE Medical Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, Wisconsin via Reference 1. Via Reference 2, the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application.

This submittal contains information which SHINE requests to be withheld from public disclosure, including proprietary information in accordance with 10 CFR 2.390(a)(4), export controlled information (ECI) in accordance with 10 CFR 2.390(a)(3), and security-related information (SRI) in accordance 10 CFR 2.390(d). SRI was identified utilizing the guidance contained in Regulatory Issue Summary (RIS) 2005-31, Revision 1. Enclosures 1 through 3 of this submittal are provided via optical storage media (OSM).

Enclosure 1 provides the non-public version of the SHINE response to the NRC staff's request for additional information. Enclosure 1 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides the public version of the SHINE response to the NRC staff's request for additional information.

YGD
NRR

Enclosures 1 and 3 contain ~~security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

Enclosure 3 provides the SHINE response to the NRC staff's request for additional information related to the SHINE Material Control and Accounting Plan. Enclosure 3 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. SHINE requests that the NRC withhold Enclosure 3, in its entirety, from public disclosure under 10 CFR 2.390.

Enclosure 4 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosures 1 and 3, pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosures 1 and 3 from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

Enclosures 1 and 3 provide the SHINE Response to the Reference (2) requests for additional information (RAIs) with the exception of RAI 4a-4 and RAI 7-1 through RAI 7-8. The SHINE Response to RAI 4a-4 will be provided by July 31, 2020. The SHINE Response to RAI 7-1 through RAI 7-8 will be provided by August 31, 2020.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on June 17, 2020.

Very truly yours,



FOR

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC
Docket No. 50-608

Enclosures

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosures 1 and 3)

ENCLOSURE 4

SHINE MEDICAL TECHNOLOGIES, LLC

**SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION RESPONSE
TO NRC'S REQUEST FOR ADDITIONAL INFORMATION**

AFFIDAVIT OF JAMES COSTEDIO

2 pages follow



AFFIDAVIT OF JAMES COSTEDIO


STATE OF WISCONSIN)
) ss.
COUNTY OF ROCK)

I, James Costedio, Vice President of Regulatory Affairs and Quality of SHINE Medical Technologies, LLC (SHINE), do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission (NRC) and apply for the withholding of information from public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial and financial information submitted in the operating license application by letter 2020-SMT-0053 with enclosures. SHINE requests that the confidential information contained in Enclosures 1 and 3 be withheld from public disclosure in their entirety.
2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.
3. Pursuant to the provisions of paragraph (a)(4) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.
 - a. The information sought to be withheld from public disclosure contained in Enclosures 1 and 3 of 2020-SMT-0053 is owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.
 - b. The information sought to be protected in Enclosures 1 and 3 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosures 1 and 3 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial financial information, commercial information, or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.
- d. The proprietary information sought to be withheld from public disclosure in Enclosures 1 and 3 includes, but is not limited to: structural configuration, primary and supporting systems of the medical isotope production facility, process and system locations, and process details. This would include information regarding the types, quantities, and locations of materials stored on site as would be referenced in facility configuration drawings. Public disclosure of the information in Enclosures 1 and 3 would create substantial harm to SHINE because it would reveal trade secrets owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality.
- e. Public disclosure of the information in Enclosures 1 and 3 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
- f. The information contained in Enclosures 1 and 3 of 2020-SMT-0053 is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC. The information is properly marked.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on June 17, 2020.



James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC